

**TRANSMITTAL LETTER TO THE UNITED  
STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

U.S. APPLICATION NO.  
(If known, see 37 C.F.R. 1.6)

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EXPRESS MAIL NO. EL 931089682 US

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/GB00/03273	25 August 2000	26 August 1999

**TITLE OF INVENTION: HEAT TRANSFER DEVICES**

**APPLICANT(S) FOR DO/EO/US: Aws Nashef; Ted Vander Wiede, ; Robert McNair; Stephen Wilson; and Simon Andrews**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1.  This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2.  This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3.  This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371 (b) and PCT Articles 22 and 39(1).
4.  A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5.  A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a.  is transmitted herewith (required only if not transmitted by the International Bureau).
  - b.  has been transmitted by the International Bureau (as noted in PCT/IB/308).
  - c.  is not required, as the application was filed in the United States Receiving Office (RO/US).
6.  A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7.  Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a.  are transmitted herewith (required only if not transmitted by the International Bureau).
  - b.  have been transmitted by the International Bureau.
  - c.  have not been made; however, the time limit for making such amendments has NOT expired.
  - d.  have not been made and will not be made.
8.  Amendments to the claims of the International Application under PCT Article 34.
  - a.  are transmitted herewith (required only if not transmitted by the International Bureau).
  - b.  have been transmitted by the International Bureau (as noted in PCT/IPEA/416).
  - c.  have not been made; however, the time limit for making such amendments has NOT expired.
  - d.  have not been made and will not be made.
9.  A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10.  A copy of the unsigned oath or declaration of the inventors. (35 U.S.C. 371 (c)(4)).
11.  A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 12. to 16. below concern other document(s) or information included:**

12.  An information Disclosure Statement under 37 CFR 1.97 and 1.98.
13.  An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
14.  A **FIRST** preliminary amendment.  
 A **SECOND** or **SUBSEQUENT** preliminary amendment.
15.  A substitute specification.
16.  A change of power of attorney and/or address letter.
17.  Other items or information:  
Certificate of Express Mailing Under 37 CFR 1.10  
Courtesy Copy of Publication PCT/GB00/03273

U.S. APPLICATION NO. (if known) 37 C.F.R. 1.10

10/069649

INTERNATIONAL APPLICATION NO.  
PCT/GB00/03273ATTORNEY'S DOCKET NUMBER:  
8830-2718.  The following fees are submitted:**Basic National Fee (27 CFR 1.492(a)(1)-(5)):**

Search Report has been prepared by the EPO or JPO ..... \$890.00

International preliminary examination fee paid to USPTO (37 CFR 1.482).....

No international preliminary examination fee paid to USPTO (37 CFR 1.482)  
but international search fee paid to USPTO (37 CFR 1.445(a)(2)).....Neither international preliminary examination fee (37 CFR 1.482) nor  
international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....International preliminary examination fee paid to USPTO (37 CFR 1.482)  
and all claims satisfied provisions of PCT Article 33(2)-(4).....

CALCULATIONS

PTO USE  
ONLY**ENTER APPROPRIATE BASIC FEE AMOUNT =****\$ 890.00**Surcharge of **\$130.00** for furnishing the oath or declaration later than 20  30  
months from the earliest claimed priority date (37 CFR 1.492(e)).**\$ 130.00**

Claims	Number Filed	Number Extra	Rate	
Total Claims	28 - 20 =	8	x \$18.00	<b>\$ 144.00</b>
Independent Claims	2 - 3 =	0	x \$84.00	\$
Multiple dependent claim(s) (if applicable)			+ \$280.00	\$
<b>TOTAL OF ABOVE CALCULATIONS =</b>				<b>\$ 1164.00</b>

Reduction by 1/2 for filing by small entity, applicable. Applicant is a Small Entity.

\$

**SUBTOTAL = \$ 1164.00**Processing fee of **\$130.00** for furnishing the English translation later than 20 30  
months from the earliest claimed priority date (37 CFR 1.492(f)).

\$

**TOTAL NATIONAL FEE = \$ 1164.00**Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an  
appropriate cover sheet (37 CFR 3.28, 3.31). **\$40.00** per property

\$

**TOTAL FEES ENCLOSED = \$ 1164.00**Amount to be  
refundedAmount to be  
charged **\$ 1164.00**a.  A check in the amount of **\$ 1164.00** to cover the above fees is enclosed.b.  Please charge my Deposit Account No. \_\_\_\_\_ in the amount of **\$** to cover the above fee. A duplicate copy  
of this sheet is enclosed.c.  The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any  
overpayment to Deposit Account No. **500573**. A duplicate of this sheet is enclosed.

SEND ALL CORRESPONDENCE TO:

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**REGISTRATION NUMBER**

10/069649

JC19 Rec'd PCT/PTO 26 FEB 2002

**PATENT**  
**Attorney Docket No.:** 8830-27

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent application of : International  
Nashef, Aws, et al. : Application No.:  
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: 25 August 2000  
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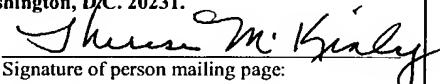
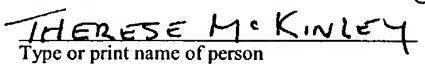
**PRELIMINARY AMENDMENT**

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Prior to examination of this application and before calculation of the filing fee, please amend the application, without prejudice, in accordance with the following.

Charge any fee or credit any overage associated with this preliminary amendment or the application filing to Deposit Account No. 500573.

<b>CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.10</b>	
EXPRESS MAIL Mailing Label Number: <u>EL 931089682 US</u>	
Date of Deposit: <u>February 26, 2002</u>	
I hereby certify that this correspondence, along with any paper referred to as being attached or enclosed, and/or fee, is being deposited with the United States Postal Service, "EXPRESS MAIL-POST OFFICE TO ADDRESSEE" service under 37 CFR 1.10, on the date indicated above, and addressed to: Commissioner for Patents, Washington, D.C. 20231.	
 Signature of person mailing page:	
 Type or print name of person	

## AMENDMENTS

Please amend the application as follows, without prejudice.

### In the Claims (Clean Copy):

1. (Amended) A catheter having a distal end and a wall, the catheter comprising a heat transfer device located approximately at its distal end, wherein the heat transfer device is engaged with the catheter wall.
2. (Amended) A catheter as claimed in Claim 1 wherein the heat transfer device is a flexible film having at least one electrical resistor flow path, which film is locatable around the catheter wall.
3. (Amended) A catheter as claimed in Claim 2 wherein the film is a flexible metal film on which the at least one electrical path has been formed.
4. (Amended) A catheter as claimed in Claim 2 wherein the at least one electrical path is located on a plastic film backing.
5. (Amended) A catheter as claimed in Claim 4 wherein the at least one electrical path is added by a deposition process.
6. (Amended) A catheter as claimed in Claim 4 wherein the at least one electrical path is added by a coating process.
11. (Amended) A catheter as claimed in Claim 10 wherein the printing process uses a conductive medium, with subsequent etching.
12. (Amended) A catheter as claimed in Claim 7 wherein a temperature sensor material is also disposed onto the catheter wall by a deposition process.

13. (Amended) A catheter as claimed in Claim 1 wherein the heat transfer device includes at least one sensing element.

14. (Amended) A catheter as claimed Claim 1 wherein at least one insulator layer is located over the resistor structure.

15. (Amended) A catheter as claimed in Claim 14 wherein the at least one insulator layer is made from parylene C.

16. (Amended) A catheter as claimed in Claim 1 wherein the heat transfer device an outwardly located layer of material selected from a group consisting of silver and gold.

17. (Amended) A catheter as claimed in Claim 1 wherein a length of the outer wall of the catheter is at least partly formed from doped material able to act as a heat transfer device upon application of power therethrough.

18. (Amended) A catheter as claimed in Claim 17 wherein the doped material is selected from a group consisting of silver and gold.

19. (Amended) A catheter having a wall the catheter comprising at least one metal wire located in at least a portion of the wall.

20. (Amended) A catheter as claimed in Claim 19 wherein the at least one wire is copper.

21. (Amended) A catheter as claimed in Claim 19 wherein the at least one wire is co-extruded within the catheter body.

22. (Amended) A catheter as claimed in Claim 19 wherein the catheter wall includes at least one set of wires.

24. (Amended) A catheter as claimed in Claim 19 wherein each wire inside the catheter wall is easily exposable.

25. (Amended) A catheter as claimed in Claim 1 wherein the catheter wall has at least one metal wire located in at least a portion of the wall.

26. (Amended) A catheter as claimed in Claim 1 wherein the catheter has a diameter of between approximately size 3 to 5 F.

27. (Amended) A catheter as claimed in Claim 1 having a single distal lumen.

28. (Amended) A catheter as claimed in Claim 27 wherein the lumen has a diameter of between approximately 0.5 to 0.7 mm.

#### REMARKS

Claims 1-28 are currently pending. By means of this preliminary amendment, claims 1-6, 11-22, 24-28 have been amended to eliminate multiple dependencies and address some minor informalities. The changes are shown in the marked-up copy of the claims that follow this amendment. No new matter has been added to the application by means of these amendments.

It is respectfully submitted that the claims presented in this preliminary amendment are patentable over the art cited during international examination.

Applicants request early examination of the application on the merits.

If the Examiner believes that direct communication with the Applicants' attorney would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the number listed below.

Respectfully submitted,  
NASHEF, AWS, ET AL.

BY: 

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**Marked-Up Copy of Amended Claims**

1. (Amended) A catheter having a distal end and a wall, the catheter comprising a heat transfer device located approximately at [or near] its distal end, wherein the heat transfer device is [layered or coated onto or into] engaged with the catheter wall.
2. (Amended) A catheter as claimed in Claim 1 wherein the heat transfer device is a flexible film having at least one [or more] electrical resistor flow path[s thereon or therethrough], which film is locatable around the catheter wall.
3. (Amended) A catheter as claimed in Claim 2 wherein the film is a flexible metal film on which the at least one [or more] electrical path[s have] has been [etched or otherwise created] formed.
4. (Amended) A catheter as claimed in Claim 2 wherein the at least one [or more] electrical path[s are] is located on [added onto] a plastic film backing.
5. (Amended) A catheter as claimed in Claim 4 wherein the at least one [or more] electrical path[s are] is added by a deposition process.
6. (Amended) A catheter as claimed in Claim 4 wherein the at least one [or] electrical path[s are] is added by a coating process.
11. (Amended) A catheter as claimed in Claim 10 wherein the printing process uses a conductive [ink or a conductive layer] medium, with subsequent etching.
12. (Amended) A catheter as claimed in [any one of Claims 7-11] Claim 7 wherein a temperature sensor material is also disposed onto the catheter wall by a deposition process.
13. (Amended) A catheter as claimed in [any one of the preceding Claims] Claim 1 wherein the heat transfer device includes at least one [or more temperature sensors or sensor leads] sensing element.

14. (Amended) A catheter as claimed [in any one of the preceding Claims] Claim 1 wherein at least one [or more] insulator layer[s] is located over the resistor structure.

15. (Amended) A catheter as claimed in Claim 14 wherein the at least one [of the] insulator layer[s] is made from parylene C.

16. (Amended) A catheter as claimed in [any one of the preceding Claims] Claim 1 wherein the heat transfer device [comprises an outer or penultimate outer] an outwardly located layer of material selected from a group consisting of silver [or] and gold.

17. (Amended) A catheter as claimed in Claim 1 wherein a length of the outer wall of the catheter is at least [wholly, substantially or] partly formed from doped material able to act as a heat transfer device upon application of power therethrough.

18. (Amended) A catheter as claimed in Claim 17 wherein the doped material is selected from a group consisting of silver [or] and gold.

19. (Amended) A catheter having a wall [wherein the catheter wall has] the catheter comprising at least one [or more] metal wire[s] located in at least a portion of the wall [therethrough].

20. (Amended) A catheter as claimed in Claim 19 wherein the [or each] at least one wire is copper.

21. (Amended) A catheter as claimed in Claim 19 [or Claim 20] wherein the [or each] at least one wire is co-extruded within the catheter body.

22. (Amended) A catheter as claimed in [any one of Claims 19-21] Claim 19 wherein the catheter wall includes at least one [or more] set[s] of wires.

24. (Amended) A catheter as claimed in [any one of Claims 19-24] Claim 19 wherein [they or] each wire inside the catheter wall is easily exposable.

25. (Amended) A catheter as claimed in [any one of Claims 1-18] Claim 1 [in combination with a catheter as claimed in any one of Claims 19-24] wherein the catheter wall has at least one metal wire located in at least a portion of the wall.

26. (Amended) A catheter as claimed in [any one of the above Claims] Claim 1 wherein the catheter has a diameter of between approximately size 3 [-] to 5 F.

27. (Amended) A catheter as claimed in [any one of the preceding Claims] Claim 1 having a single distal lumen.

28. (Amended) A catheter as claimed in Claim 27 wherein the lumen has a diameter of between approximately [0.5-07] 0.5 to 0.7 mm.

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1

JC10 Rec'd PCT/PTO 26 FEB 2002

1 "HEAT TRANSFER DEVICES"

2

3 The present invention relates to improvements for  
4 catheters having a heat transfer device at or near  
5 their distal end.

6

7 One of the present constraints concerning manufacture  
8 of catheters designed to monitor various cardiac  
9 output data is the manner and form of the required  
10 heat transfer device system. One present form of  
11 heat transfer device involves a thermal coil radially  
12 disposed about the catheter body to form a generally  
13 tubular coil which extends along the outside wall of  
14 the catheter. Such a heat transfer device is shown  
15 in US 5509424. However, such heat transfer coils  
16 require time and effort to wind and form and also  
17 restrict the possible miniaturisation of such  
18 catheters for use in paediatrics.

19

1 It is an object of the present invention to provide  
2 improvements to the manner and nature of heat  
3 transfer devices for use with catheters.

4

5 Thus, according to one aspect of the present  
6 invention, there is provided a catheter having a heat  
7 transfer device at or near its distal end, wherein  
8 the heat transfer device is layered or coated onto or  
9 into the catheter wall.

10

11 In one embodiment, the heat transfer device is a  
12 flexible film having one or more electrical resistor  
13 flow paths thereon or therethrough, which film is  
14 locatable around the catheter wall.

15

16 Such films can include flexible metal films on which  
17 one or more electrical paths have been etched or  
18 otherwise created. Alternatively, one or more  
19 electrical paths could be added onto a plastic film  
20 backing. The form of addition includes any type of  
21 deposition or coating, and the one or more electrical  
22 paths could be formed by etching, etc to form the  
23 resistor structure.

24

25 One or more temperature sensors or sensor leads could  
26 be included on or within the heat transfer device  
27 film to monitor the temperature of the electrical  
28 path(s), and thus the temperature of the overall heat  
29 transfer device.

30

1 Suitable backing materials include PVC, polyurethane,  
2 silk, synthetic silk, silicon rubber, Elaston™ etc,  
3 possibly about 20-80 microns thick, and suitable thin  
4 high resistant metal films include nickel, chromium  
5 or nickel-chromium. These can be deposited on the  
6 plastic backing material, and patterned using a  
7 photolithography mask to form the resistor structure.  
8

9 On top of the resistor structure could be located a  
10 suitable insulator like parylene C, followed by  
11 deposition of a suitable temperature sensing means  
12 e.g. thermistors or platinum. Finally the outer  
13 surface may be coated with a silver or gold layer,  
14 possibly 5-10 microns thick. This layer assists in  
15 averaging heat distribution. Gold and/or silver are  
16 suitable as they are conductive and biocompatible.  
17 Optionally a further layer of parlyene C or other  
18 insulation is added as the outer layer.

19  
20 Possible arrangements for the electrical paths and  
21 temperature sensing means across the backing material  
22 are shown in Figures 3 and 4 of the accompanying  
23 drawings.

24  
25 This form of heat transfer device can be fixed around  
26 a catheter at or near its distal end. Preferably the  
27 film is about 0.5-2.0 cm long, in order for it to  
28 remain within the main pulmonary artery trunk. The  
29 film could be fixed around the catheter starting at  
30 about 4-5 cm from the tip, and in the case of a PVC

1       catheter body, the PVC film heat transfer device  
2       could be bonded by solvent.

3

4       Such a heat transfer device could be adapted to fit a  
5       catheter less than 7F diameter (2.3mm). More  
6       preferably the heat transfer device can be  
7       incorporated in a catheter of 3-5F (1-1.67mm)  
8       diameter. The heat transfer device should not  
9       increase the outer diameter of the catheter more than  
10      about 0.3F (0.1mm).

11

12      Using the same technique, a similar film could be  
13      formed purely for temperature sensing. The  
14      temperature sensing material could be deposited on a  
15      backing film, followed by parylene (and gold)  
16      coatings. Such a temperature sensor could be  
17      positioned to 2-4 cm proximal to the heat transfer  
18      device. Optionally a further layer of parylene C or  
19      other insulation is added as the outer layer.

20

21      According to another embodiment of the present  
22      invention, the heat transfer device is disposed onto  
23      the catheter wall by any known method of deposition,  
24      eg plasma deposition, printing, electroplating onto  
25      plastic, photo lithography etc. Application by  
26      printing uses eg conductive ink, or a conductive  
27      layer, with subsequently etching. This method of  
28      deposition can use any suitable resistive material.  
29      In addition, the temperature sensor material could be  
30      similarly applied.

31

1 According to a second aspect of the present  
2 invention, there is provided a catheter having a  
3 length of its outer wall formed wholly, substantially  
4 or partly from doped material able to act as a heat  
5 transfer device upon application of power  
6 therethrough.

7

8 This form of heat transfer device could be formed as  
9 an inherent part of the catheter wall, rather than as  
10 a separate addition of a heat transfer device to the  
11 catheter. The catheter wall is sufficiently doped  
12 with a resistive material or ingredient able to pass  
13 electrical current therethrough, without affecting  
14 its other properties. Any conductive material could  
15 be suitable, eg silver, gold.

16

17 According to a third aspect of the present invention,  
18 there is provided a catheter wall having one or more  
19 metal wires therethrough.

20

21 By locating the electrical connections within the  
22 catheter body wall, separate lumens for electrical  
23 connections to its distal end within the catheter  
24 interior are no longer required. These wires can  
25 also provide the catheter with the desired or  
26 required stiffness.

27

28 The wire(s) can be formed from any suitable metal, eg  
29 copper. Preferably, each wire is co-extruded within  
30 the catheter body.

31

1 More preferably, there are one or more sets of  
2 electrical wires in the catheter wall, each set  
3 having the required number of wires for the desired  
4 operations.

5

6 In one embodiment of the present invention, the  
7 catheter body has three sets of wires, each set  
8 comprising two wires. One set of wires is for a  
9 heating element, and the other two sets are for each  
10 of two temperature sensing elements located on or  
11 along the catheter wall, or one set for measuring  
12 ambient blood temperature, and the other set for  
13 measuring the temperature of the heat transfer  
14 device, or any other suitable combination of  
15 measurements.

16

17 The wire or wires inside the catheter wall should be  
18 easily exposable and thus connectable to the required  
19 electrical units to which they correspond. Any  
20 exposed wire could be covered by a suitable insulator  
21 such as vinyl adhesive, or urethane potting compound.

22

23 An example of this aspect of the present invention is  
24 shown in Figure 2 of the accompanying drawings.

25

26 According to a preferred embodiment of the present  
27 invention, there is provided a catheter combining the  
28 first and third aspects described above.

29

30 One advantage of the use of one or more aspects of  
31 the present invention as described above is the

1 ability to reduce the size of the catheter, more  
2 particularly for paediatric use. A catheter wherein  
3 the electrical wires required for the heat transfer  
4 device, etc are co-extruded within the catheter body,  
5 means that the catheter may only need a single distal  
6 lumen, (possibly 0.5-0.7 mm diameter) for solution  
7 infusion and pressure monitoring.

8

9 The novel apparatus and methods of the present  
10 invention could also be used in non-medical fields  
11 using heat transfer devices at or near the distal  
12 ends of elongate tubing to be located in remote  
13 locations. Such fields include aeronautics, any  
14 fluid flow analysis, food and drink processing and  
15 monitoring, water and sewerage management, chemical  
16 engineering, fuel supply to engines, etc.

17

18 The present invention is also particularly applicable  
19 to the paediatric catheter field.

20

21 Embodiments of the present invention are shown by way  
22 of example only in the accompanying diagrammatic  
23 drawings in which:

24

25 Figure 1 is side view of a paediatric catheter;

26

27 Figure 2 is a radial cross-sectional view of a  
28 catheter wall having electrical wires located  
29 therein;

30

1      Figure 3 is an example of a heat transfer device film  
2      for application around a catheter body;

3

4      Figure 4 is an example of a temperature sensor for  
5      application around a catheter body.

6

7      Figure 5 is a longitudinal cross-sectional view of a  
8      catheter body having a heat transfer device  
9      therearound.

10

11     Figures 6a, b and c show a method of preparing a  
12     catheter having a heat transfer device.

13

14     The dimensions referred to in relation to  
15     accompanying diagrammatic drawings are illustrative  
16     only, and in no way limiting or essential.

17

18     Referring to the drawings, Figure 1 shows the general  
19     form of a paediatric pulmonary artery catheter, which  
20     may be 70-100 cm long. At one end, such catheters  
21     generally have a connection 2, for example, to a  
22     TRUCCOM™, and a distal lumen 4. Such catheters are  
23     generally 3-5F size, i.e. approximately 1-1.67mm  
24     diameter.

25

26     For all such catheters, the heat transfer device  
27     should preferably be in the range 0.5-2.0 cm long in  
28     order to remain within the main pulmonary artery  
29     trunk. The catheter body shore hardness should be  
30     about 45-55D for proper handling during insertion

1 into patients. Use of softer materials may be  
2 possible, but may require the additional use of a  
3 wire to stiffen the catheter body allowing  
4 manoeuvrability during insertion.

5

6 In the versions of the present invention based on the  
7 layering or coating of the transfer device onto or  
8 into the catheter wall, the heat transfer device  
9 should not increase the outer diameter of the  
10 catheter more than 0.3F (0.1mm).

11

12 Figure 1 shows a schematic representation of a heat  
13 transfer device 6 according to the present invention  
14 2cm long, and located 4cm from the end of the  
15 catheter. Thereafter is located a temperature sensor  
16 8, approximately 0.3cm long.

17

18 Figure 2 is a cross-section of a catheter wall 10  
19 wherein six copper wires 12 are co-extruded with the  
20 catheter body so as to be located in the catheter  
21 wall 10. Of the six wires, two are located for the  
22 heating element, and two for each of two temperature  
23 sensing elements (not shown). Thus, the catheter  
24 only has a single distal lumen 14, 0.5mm diameter for  
25 solution infusion and pressure monitoring.

26

27 Figure 3 is an example of a flexible metal film heat  
28 transfer device 20 according to the present  
29 invention. The film consists of a thin high  
30 resistance metal film, e.g. of nickel, chromium or  
31 nickel-chromium, deposited on a PVC film 22, e.g. of

1 25-50 microns thick. The resistor wire 24 in Figure  
2 3 can be patterned using a photolithography mask.  
3 The device 20 includes temperature sensor leads 26.  
4

5 Figure 4 shows a possible pattern for temperature  
6 sensor leads 30 on a similar PVC film 32 to act as a  
7 temperature sensor as shown in Figure 1. It is  
8 similarly made to the device in Figure 3, but only  
9 the temperature sensing material is deposited  
10 followed by Paralyene C and gold coatings.

11

12 Figure 5 shows a longitudinal cross-section of a  
13 catheter having a heat transfer device 34 based on  
14 that shown in Figure 3. Around the catheter body 36  
15 is a PVC film 0.05mm thick. The resistor and  
16 temperature sensor leads are on the PVC film, which  
17 is then coated with a suitable insulator such as  
18 Parylene C, possibly of 0.005mm thickness. The outer  
19 surface is coated with a silver or gold layer  
20 (suitably 5-10 microns thick).

21

22 As shown in Figures 6a-6c the overall heat transfer  
23 device 34 can be conjoined with the catheter body 36  
24 using any suitable means such as a solvent. A  
25 temperature sensor 40 such as that shown in Figure 4  
26 is also conjoined with the catheter body 36, e.g. 2-4  
27 cm proximal to the device 34. Thereafter, and as  
28 shown in Figures 6a-c, the wires 38 inside the  
29 catheter wall 36 are then exposed and the heat and  
30 temperature sensing wires are then connected and

1 covered by a vinyl adhesive or another suitable  
2 insulator.

3

4

1      Claims

2

3      1. A catheter having a heat transfer device at or  
4      near its distal end, wherein the heat transfer  
5      device is layered or coated onto or into the  
6      catheter wall.

7

8      2. A catheter as claimed in Claim 1 wherein the  
9      heat transfer device is a flexible film having  
10     one or more electrical resistor flow paths  
11     thereon or therethrough, which film is locatable  
12     around the catheter wall.

13

14     3. A catheter as claimed in Claim 2 wherein the  
15     film is a flexible metal film on which the one  
16     or more electrical paths have been etched or  
17     otherwise created.

18

19     4. A catheter as claimed in Claim 2 wherein the one  
20     or more electrical paths are added onto a  
21     plastic film backing.

22

23     5. A catheter as claimed in Claim 4 wherein the one  
24     or more electrical paths are added by a  
25     deposition process.

26

27     6. A catheter as claimed in Claim 4 wherein the one  
28     or electrical paths are added by a coating  
29     process.

30

- 1       7. A catheter as claimed in Claim 1 wherein the  
2           heat transfer device is disposed directly onto  
3           the catheter wall.
- 4
- 5       8. A catheter as claimed in Claim 7 wherein the  
6           heat transfer device is disposed onto the  
7           catheter wall by a deposition process.
- 8
- 9       9. A catheter as claimed in Claim 8 wherein the deposition process is a plasma deposition process.
- 10
- 11      10. A catheter as claimed in Claim 8 wherein the deposition process is a printing process.
- 12
- 13      11. A catheter as claimed in Claim 10 wherein the printing process uses a conductive ink or a conductive layer, with subsequent etching.
- 14
- 15      12. A catheter as claimed in any one of Claims 7-11 wherein a temperature sensor material is also disposed onto the catheter wall by a deposition process.
- 16
- 17      13. A catheter as claimed in any one of the preceding Claims wherein the heat transfer device includes one or more temperature sensors or sensor leads.
- 18
- 19
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- 29

- 1 14. A catheter as claimed in any one of the  
2 preceding Claims wherein one or more insulator  
3 layers are located over the resistor structure.  
4
- 5 15. A catheter as claimed in Claim 14 wherein one of  
6 the insulator layers is parylene C.  
7
- 8 16. A catheter as claimed in any one of the  
9 preceding Claims wherein the heat transfer  
10 device comprises an outer or penultimate outer  
11 layer of silver or gold.  
12
- 13 17. A catheter as claimed in Claim 1 wherein a  
14 length of the outer wall of the catheter is  
15 wholly, substantially or partly formed from  
16 doped material able to act as a heat transfer  
17 device upon application of power therethrough.  
18
- 19 18. A catheter as claimed in Claim 17 wherein the  
20 doped material is silver or gold.  
21
- 22 19. A catheter wherein the catheter wall has one or  
23 more metal wires therethrough.  
24
- 25 20. A catheter as claimed in Claim 19 wherein the or  
26 each wire is copper.  
27
- 28 21. A catheter as claimed in Claim 19 or Claim 20  
29 wherein the or each wire is co-extruded within  
30 the catheter body.  
31

- 1 22. A catheter as claimed in any one of Claims 19-21  
2 wherein the catheter wall includes one or more  
3 sets of wires.
- 4
- 5 23. A catheter as claimed in Claim 22 wherein the  
6 catheter body has three sets of wires, each set  
7 comprising two wires.
- 8
- 9 24. A catheter as claimed in any one of Claims 19-24  
10 wherein they or each wire inside the catheter  
11 wall is easily exposable.
- 12
- 13 25. A catheter as claimed in any one of Claims 1-18  
14 in combination with a catheter as claimed in any  
15 one of Claims 19-24.
- 16
- 17 26. A catheter as claimed in any one of the above  
18 Claims of size 3-5F.
- 19
- 20 27. A catheter as claimed in any one of the  
21 preceding Claims having a single distal lumen.
- 22
- 23 28. A catheter as claimed in Claim 27 wherein the  
24 lumen has a diameter of approximately 0.5-07 mm.

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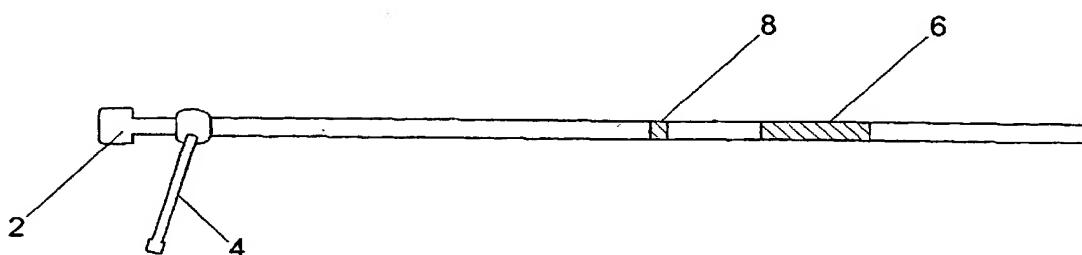
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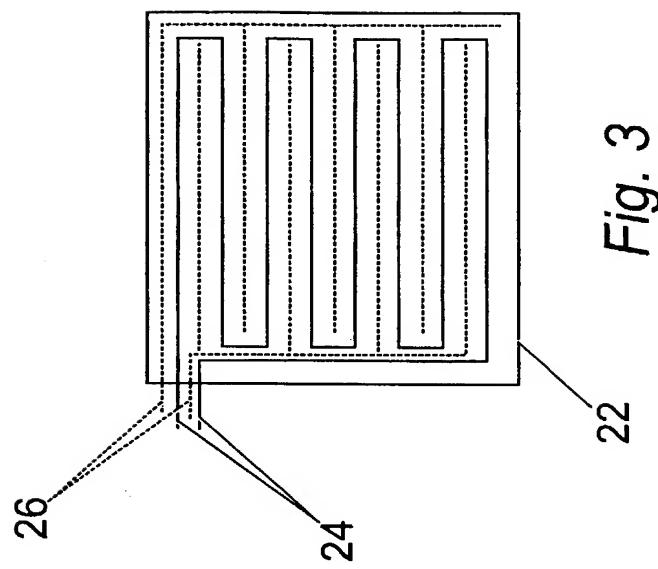
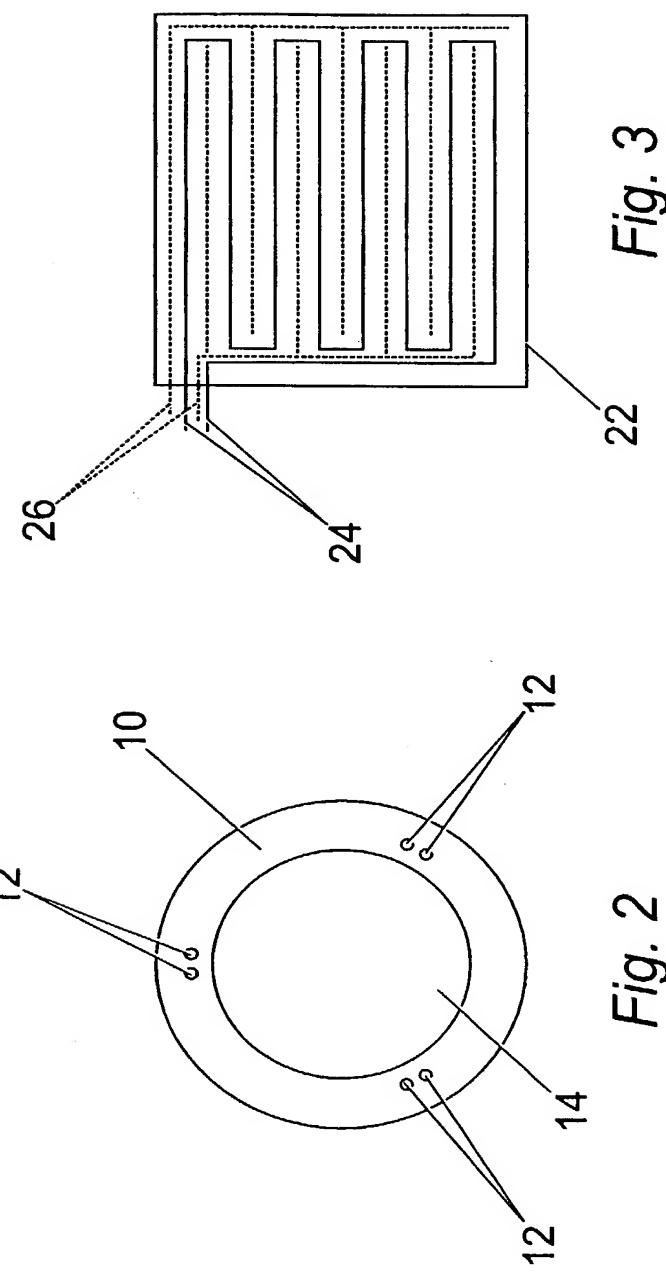
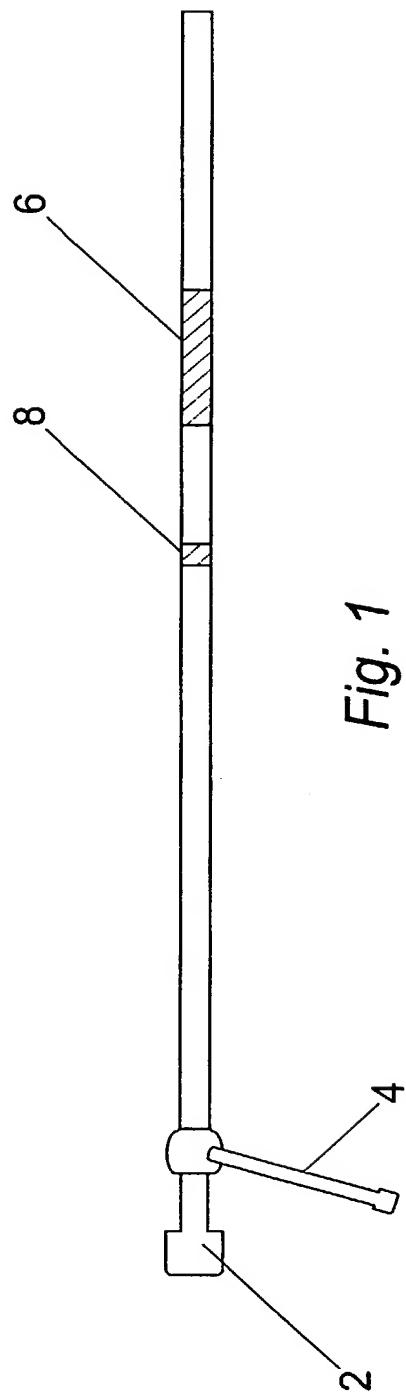
(54) Title: HEAT TRANSFER DEVICES



WO 01/13808 A1

(57) Abstract: A catheter having a heat transfer device at or near its distal end, wherein the heat transfer device is layered or coated onto or into the catheter wall is described. The heat transfer device is preferably a flexible film having one or more electrical resistor flow paths thereon or therethrough, or is disposed directly onto the catheter wall by a deposition process. The heat transfer device may alternatively be formed by a length of the catheter wall being formed wholly, substantially or partly from doped material able to act as a heat transfer device upon application of power therethrough. The heat transfer device is preferably powered by one or more metal wires co-extruded within the catheter body.

1 / 3



2 / 3

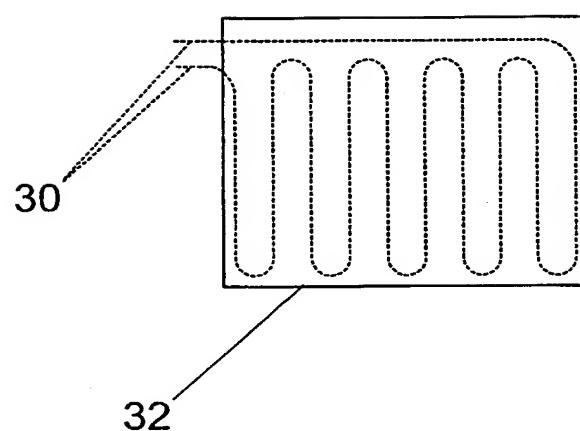


Fig. 4

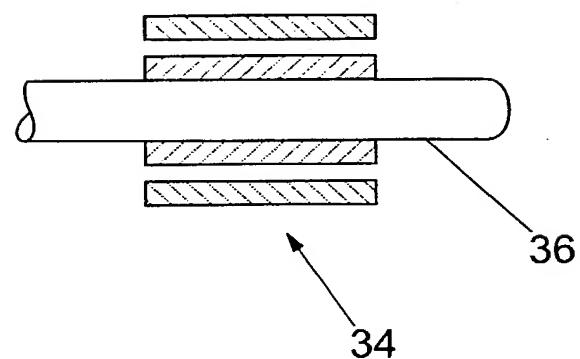


Fig. 5

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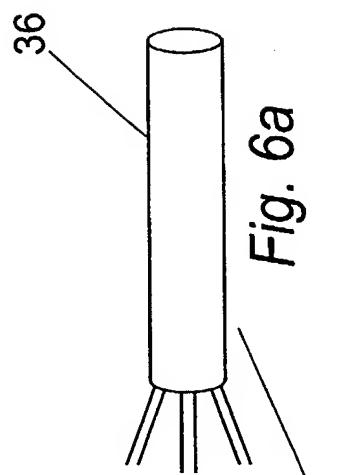


Fig. 6a

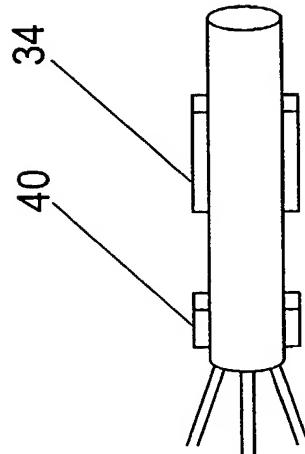


Fig. 6b

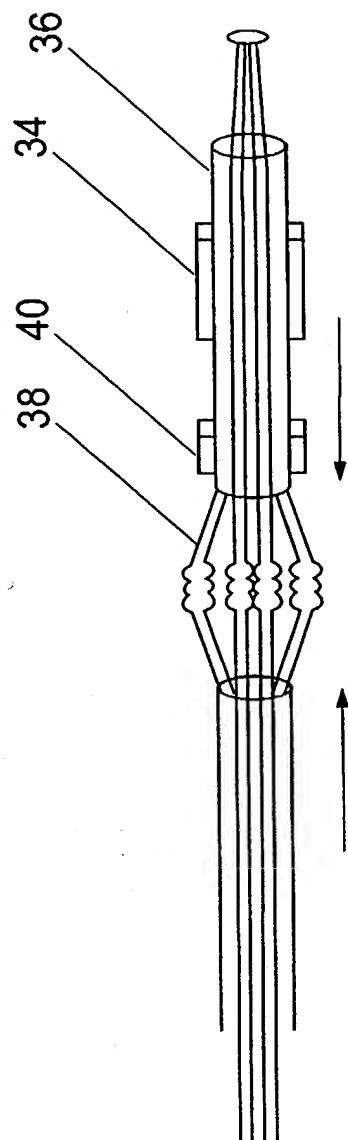


Fig. 6c

**PATENT**  
Attorney Docket No. 8830-27

**DECLARATION AND POWER OF ATTORNEY**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are stated below next to my name:

I believe I am the original, first, and sole inventor (if only one name is listed below) or an original, first, and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

---

**HEAT TRANSFER DEVICES**

---

the specification of which was filed on August 25, 2000 as PCT Application No. PCT/GB00/03273 and amended on February 26, 2002 (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with 37 CFR §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT international application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed:

**PRIOR FOREIGN/PCT APPLICATION(S)**

<u>COUNTRY/OFFICE</u>	<u>APPLICATION NO.</u>	<u>DATE OF FILING</u>	<u>PRIORITY CLAIMED</u>
United Kingdom	9920112.1	August 26, 1999	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

PROVISIONAL APPLICATION NUMBER : DATE OF FILING

60/153,414

September 10, 1999

I hereby claim the benefit under 35 U.S.C. §120 of any United States application(s) or §365(c) of any PCT International application(s) designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose material information as defined in 37 CFR §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

**PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS  
DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. §120**

<u>Application Serial No.</u>	<u>Date of Filing</u>	<u>Patented</u>	<u>Pending</u>	<u>Abandoned</u>	<u>Status (check one)</u>
NONE		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

And I hereby appoint Arthur H. Seidel, Registration No. 15,979; Gregory J. Lavorgna, Registration No. 30,469; Daniel A. Monaco, Registration No. 30,480; Thomas J. Durling, Registration No. 31,349; John J. Marshall, Registration No. 29,671; Joseph R. DelMaster, Jr., Registration No. 38,123; Robert E. Cannuscio, Registration No. 36,469; and George A. Frank, Registration No. 27,636, my attorneys or agents with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

1-00

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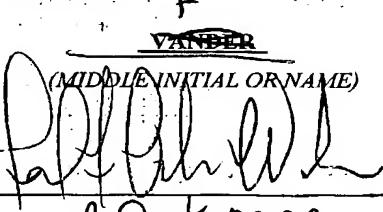
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